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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/659,598	09/10/2003	Miri Seiberg	JBP-430-CIP1	5368
27777	7590	01/05/2006	EXAMINER	
PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			GEMBEH, SHIRLEY V	
			ART UNIT	PAPER NUMBER
			1614	

DATE MAILED: 01/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/659,598

Applicant(s)

SEIBERG ET AL.

Examiner

Shirley V. Gembeh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 June 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of claims

Claims 1-10 are pending.

Claims 1-10 are rejected.

Response to Amendment

In response to the Office Action dated June 08, 2005, Applicant provided arguments supporting the patentability of the above claims in the transmittal of a response June 08, 2005, Office Action Under 37 CFR § 1.111 filed October 24, 2005.

Double Patenting

The rejection of claims 1-10 under Double Patenting is moot in view of the Terminal Disclaimer filed October 24, 2005.

New Rejection Claim Rejections - 35 USC § 112-First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

- I. Claim 1 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for botanical families of leguminosae, solanaceae, gramineae, and cucurbitaceae, does not reasonably provide enablement for all nondenatured botanical extract. The specification does not enable any person skilled in

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the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

In evaluating the enablement question, several factors are to be considered.

Note *In re Wands*, 8 USPQ2d 1400 and *Ex parte Forman*, 230 USPQ 546. The factors include: 1) The nature of the invention, 2) the state of the prior art, 3) the predictability or lack thereof in the art, 4) the amount of direction or guidance present, 5) the presence or absence of working examples, 6) the breadth of the claims, 7) the relative skill of those skilled in the art and 8) the quantity of experimentation needed.

1) The nature of the invention: The method of use claims are drawn to topically administering a nondenatured botanical extract but in view of the report *Botanical.com A modern Herbal*: indicates (see page 1, 2nd paragraph) that the sap of poison Ivy is extremely poisonous (thus sap is nondenatured), which does not support applicants' claims in treating skin conditions with nondenatured botanical extract.

2) The state of the prior art: The report (see page 1 *Botanical.com A modern Herbal*) suggests that not all nondenatured botanical extracts are used for the treatment of skin conditions and in order to use all nondenatured botanical extracts requires an undue amount of research to successfully attain that goal.

3) The predictability or lack thereof in the art: On page 23 of applicants' specification lines 1-30 did not show total treatment with nondenatured botanical extracts.

4) The amount of direction or guidance present -The specification only provides few examples and no evidence of complete treatment in the examples provided, the examples will not enable one skilled in the art to use all nondenatured botanical

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extracts, 5) the presence or absence of working examples: The examples shown did not convey that all nondenatured botanical abstract can be used for the treatment of skin conditions. In addition there is no apparent guidance as to what to expect when any nondenatured botanical extract is used for treating skin conditions.

6) The breadth of the claims: The claims are drawn to methods of treating.

7) The quantity of experimentation needed would be an undue burden since there is inadequate guidance given to the skilled artisan for the reasons stated above.

8) The relative skill of those skilled in the art. Based on the unpredictable nature of the invention, one skilled in the art would not have envisioned practicing the invention without the exercise of undue experimentation burden.

Thus, factors such as "sufficient working examples", "the level of skill in the art" and "predictability", etc. have been demonstrated to be sufficiently lacking in the instant case for the instant method claims.

In consideration of each of factors 1-8, it is apparent that there is undue experimentation because of variability in prediction of outcome that is not addressed by the present application disclosure, examples, teaching and guidance presented. Absent factual data to the contrary, the amount and level of experimentation needed is undue and the resultant outcome not predictable.

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. To satisfy the written description requirement, applicant must convey with reasonable clarity to one skilled in the art, as of the filing date that application was in possession of

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the claimed invention. There is no description in the specification for ring systems of formula I contemplated.

Claims employing method for treating skin condition with synthetic retinoids are not described, nor exemplified, nor does the specification inform the public of the limits of the monopoly asserted. The expression provided in the specification on page 11 lines 14-25 represents only a generic formulation regarding the possible molecule synthetic retinoids claimed in the instant application.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shirley V. Gembel whose telephone number is 571-272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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